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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/576,424	05/22/2000	Darrell R. Anderson	012712-855	2393

909 7590 09/07/2005

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EXAMINER

GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/576,424

Applicant(s)

ANDERSON ET AL.

Examiner

Phillip Gambel

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11,12,19,20 and 27-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11,12,19,20,27-37, 39-48 and 50-55 is/are allowed.
- 6) ☒ Claim(s) 38 and 49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 7/26/05 has been entered.

Applicant's amendment, filed 7/26/05, has been entered.

Claims 19, 34, 35, 39, 42, 44-46, 50, 53 and 55 have been amended.

Claims 11-12, 19-20 and 27-55 are pending.

Claims 1-10, 13-18 and 21-26 have been canceled previously.

2. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The amendment filed 7/26/05, is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

Amended SEQ ID NOS: 9 and 10, including the Substitute Sequence Listing and corresponding computer readable form as well as informal replacement figures for Figure 5A.

As applicant acknowledges, the above-mentioned changes correspond to a corrected sequence of the 16C10 light chain antibody.

Applicant's statement through their attorney that the nucleotide and amino acid sequence of the ATCC Deposit Accession No. HB-12119 is the same as the sequence filed in the substitute Sequence Listing submitted and do not constitute new matter is acknowledged.

However in the interest of clarifying the record, applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the corrected sequence of the 16C10 light chain antibody are indeed the correct sequences of the 16C10 light chain specifically identified in the application as filed.

The provision of the appropriate declaration would obviate this objection as well as the rejection under 35USC 112, first paragraph, new matter below.

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It is also noted that there is a handwritten correction ("Ser" to "Ala") in the III. Remarks Section of applicant's amendment; yet this handwritten correction is not initialed.

Alternatively, applicant is required to cancel the new matter in the reply to this Office Action.

4. Claims 38 and 49 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. The specification as originally filed does not provide support for the invention as now claimed: "SEQ ID NOS: 9 and 10".

Applicant's amendment, filed 7/26/05, including applicant's statement through their attorney that the nucleotide and amino acid sequence of the ATCC Deposit Accession No. HB-12119 is the same as the sequence filed in the substitute Sequence Listing submitted and do not constitute new matter is acknowledged.

However in the interest of clarifying the record as pointed out above, applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the corrected sequence of the 16C10 light chain antibody are indeed the correct sequences of the 16C10 light chain specifically identified in the application as filed.

Therefore, the corrected sequences are deemed new matter.

The specification as filed does not provide a written description nor sufficient blazemarks and direction for the instant methods encompassing the above-mentioned "corrected sequences to the 16C10 light chain", as currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office Action

Alternatively, applicant is invited to provide sufficient written support for the "corrected sequences" or provide the appropriate statement from a person in a position to corroborate the fact, as indicated above.

5. Claims 32 - 33 are objected to because the claims should recite "anti-CD54 antibody", "anti-CD11 antibody", "anti-CD11a antibody" and "anti-IL-1 antibody" for clarity, rather than the current recitation which does not include the designation of these molecules as antibodies.

6. As indicated previously, the instant claims drawn to Crohn's disease by administering an anti-CD80 or a CD80-binding fragments thereof sufficient to inhibit the binding of B cell and T cells via the CD80/CD28 pathways, where said antibody or fragment thereof binds specifically to CD80 antigen without inhibiting the binding of CD80 antigen to CTLA-4 appears free of the prior art.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
September 6, 2005